For use by us distributors and ma **MANDATOR**



Page __ of _2_ FDA Use Only MEDICAL PRODUCTS REPORTING C. Suspect medication(s) A. Patient information 1. Name (give labeled strength & mfr/labeler, if known) 3. Sex 4. Weight 1. Patient identifier 2. Age at time #1 TRAMADOL (TRAMADOL) female of event: 17 Year(s) lbs UNKNOWN or UNK X male #2 TYLENOL PM (ACETAMINOPHEN/DIPHENHYDRAMINE) Date -kgs In confidence of birth: 2. Dose, frequency & route used 3. Therapy dates (if unknown, give duration) B. Adverse event or product problem Unknown, Unknown, ORAL from/to (or best estimate) Product problem (e.g., defects/malfunctions) I. X Adverse event and/or #1 ??/??/?? - ??/??/??: 2. Outcomes attributed to adverse event #2 Unknown, hs,ORAL #2 ??/??/?? - ??/??/?? disability (check all that apply) 4. Diagnosis for use (indication) 5. Event abated after use congenital anomaly death stopped or dose reduced #1 pain, including headaches, leg (mw/day/ye) Trequired intervention to prevent cramps, backache #1 yes no K doesn't life-threatening permanent impairment/damage *2 sleep disturbance other: | hospitalization - initial or prolonged no X doesn't 7. Exp. date (if known) 6. Lot # (if known) 4. Date of 3 Date of #1 UNK #1 UNK Event reappeared after this report 08/12/98 event UNK reintroduction #1 yes no X doesn't (midday/yr) #2 UNK #2 (INK 5. Describe event or problem NDC # - for product problems only (if known) A report from a medical toxicologist of a case involving a 17 year old male who was hospitalized with elevated liver function tests renal insufficiency elevated UNK Concomitant medical products and therapy dates (exclude treatment of event)
 NONE ??/??/?? - ??/??/?? lipase, rhabdomyolysis, and thrombocytopenia. A urine toxicology screen revealed acetaminophen, diphenhydramine, and Tramadol.A plasma APAP level was 6 ug/ml. The patient has been taking Tramadol for pain for one month. In addition, he was taking Tylenol PM (acetaminophen/diphenhydramine) at HS and occasional Tylenol (acetaminophen) for aches and pains. No doses provided The initial liver function tests, elevated lipase, thrombocytopenia and evidence of rhabdomyolysis lined. A modest elevation of LFT's persists (approx. 400 G. All manufacturers e), the creatinine remains elevated and the patient has 1. Contact office - name/address (& mfring site for devices) 2. Phone number to undergo repeat dialysis. This patient has a history of R. W. JOHNSON PHARM. RESEARCH INSTITUTE (908) 704-4600 for brain injury. DIV. OF ORTHO PHARMACEUTICAL CORPORATION 3. Report source (check all that apply) Follow-up received 06-AUG-98 from toxicologist: The patient is ROUTE 202, P.O. BOX 300 now off dialysis with recovering renal function, and is in RARITAN NJ 08869-0602 foreign the neuro rehabilitation unit improving As of 29-JUL-98 ALT was continuing in the '100's'. Provided indication for use and (Informing unit) study concomitant medication information. literature consumer health professional 4. Date received by manufacturer (mu/day/yr) (A)NDA # 20-281 user facility 08/06/98 IND# company representative 6. Relevant tests/laboratory data, including dates 6. If IND, protocol # plasma APAP level 6 ug/ml, elevated creatinine (NOS), no initial LFT's provided- subsequent LFT (400 range)distributor pre-1938 yes [unspecified __ other: 7. Type of report OTC (check all that apply) Follow-up received 06-AUG-98: ALT continues in *100's* yes product 5-day 💢 15-day 8. Adverse event term(s) 1) RENAL FAILURE ACUTE 10-day periodic 2) RHABDOMYOLYSIS 3) HEPATIC ENZYMES INCREASED 🗌 Initial 💢 follow-up # 1 4) THROMBOCYTOPENIA 5) ENZYME ABNORMALITY 7. Other relevant history, including preexisting medical conditions (e.g., allergies, 9. Mfr. report number race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) 980713-107012507 history of prior brain injury E. Initial reporter Name, address & phone #
TOXICOLOGIST Follow-up received 06-AUG-98:headaches,leg cramps,backache CENTER Phone # : n) 1998 Initial reporter also sent report to FDA 2. Health professional? 3 Occupation Physician Submission of a report does not constitute an 💹 yes 🗌 no admission that medical personnel, user facility, yes no 🛛 unk distributor, manufacturer or product caused or

contributed to the event.

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. FDA MEDICAL	PRODUCTS REPOR	RTING PROG	RAM	Page	_2_ of _2_		<u> </u>	Use Only
A. Patient info	ormation				C. Suspect medica	ition(s)		
1. Patient identifier 2. Age at time 3. Sex 4. Weight					1. Name (give labeled strength & mfr/labeler, if known)			
1. I aben identities	of event:		female	lbs	#3 TYLENOL (ACETAMIN	OPHEN)		
	or ———			or				
1	Date		maJe	kgs	#4			
In confidence	of birth:	ara blom			2. Dose, frequency & route	used		es (if unknown, give duration)
	ent or product	problem		1 15	Unknown, PRN, Unki		From/to (or hest es	
1. Adverse even	t and/or 🗍 Pt	roduct problem	(e.g., detects	/mairuncuons)	<u>‡3</u>		#3 ??/??/??	- ??/??/??
2. Outcomes attribut		disability			#4		#4	
(check all that appl	y) -	congenita	l anomaly		4. Diagnosis for use (indica	ation)		5. Event abated after use
death	(mo/duy/yr)		ntervention to	prevent	#3 aches and pains			stopped or dose reduced
life-threatening			t impairment/d					#3 yes no No doesn't
hospitalizatio	n - initial or protonged	other:			#4			#4 yes no doesn't
		15			6. Lot # (if known)		. date (if known)	apply .
3. Date of event		4. Date of this report			#3 UNK	#3 UN	K	8. Event reappeared after
(molday/yr)		(moldaylyr)			#4	#4		reintroduction
5. Describe event or	problem				9. NDC # - for product prol	blems only (if known)	yes no doesn't
					9. NEC # - Tor product prof	oicins only (ii kilowii)	#4 yes no doesn't
					NA			арріу
				1	10. Concomitant medical p	roducts an	id therapy dates (ex	clude treatment of event)
1					The state of the s			
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						*		
					1			요 . 그는 그 전 시민 선생님이 없다.
					G. All manufactur	rers		
					I. Contact office - name/ad	dress (& mi	fring site for device	s) 2. Phone number
			•		R. W. JOHNSON PHARM			(908) 704-4600
1				ļ	DIV. OF ORTHO PHARM		CORPORATION	3. Report source
				İ	ROUTE 202, P.O. BOX RARITAN NJ 08869-			(check all that apply)
				ļ	1			foreign
					(Informing unit)			study
				1	1			literature
								consumer
								health
				1	4. Date received by manufa	cturer 5.		— professional
	,			1	(mu/day/yr)	(A))NDA #	user facility
C. Dalamant sastaffah	poratory data, includio	ng dates					IND#	company representative
O. Kelevant tests/130	ocatory data, mendon	ing dates		1	6. If IND, protocol #		PLA#	- représentative
1				1	İ			distributor
					7. Type of report		pre-1938	yes other:
					(check all that apply)		OTC	
					5-day 15-day	<u> </u>	product	
						8.	Adverse event ter	.m(s)
					10-day periodic			
İ					Initial follow-up	#		
			7-			<u></u>		
7. Other relevant b	istory, including preex smoking and alcohol use	isting medical d henatic/renal d	vsfunction, etc.	g., attergres,	9. Mfr. report number			
race, pregnancy, s	SHOKING and account ase	,	,	•		1		
					E. Initial reporter			
1					1. Name, address & phon	e #		
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1				ļ		•		
				Í				3 2 0 1998
				į				· ~ ·
· <u></u>					2. Health professional?	3. Occupa	tion	4. Initial reporter also
	Submiss	ion of a report on that medical	does not const	titute an	yes no	J. Occupa		4. Initial reporter also sent report to FDA
	admissid distribu	on that medical tor, manufactu	rer or produc	caused or	ال 503 ال			yes no unk
Form 3500A Facsimi		ited to the even						